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10/667,580	09/22/2003	David S. Haffner	GLAUKO.035A	9637

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/667,580	Applicant(s) HAFFNER ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 13-36 is/are pending in the application.
- 4a) Of the above claim(s) 21-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 21-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
2. The newly presented claims are related as to the originally examined claims as a subcombination of the more generic combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the subcombination claims a self-trephinating distal portion and does NOT claim the dimensions that allow the originally examined implant to extend between the anterior chamber and Schlemm's canal. The subcombination has separate utility such as an implant that may be placed between the anterior chamber and a vascular drainage pathway rather than through the trabecular meshwork.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or

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includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,544,249 to Yu et al in view of US 6,626,858 to Lynch et al.

In the specification and figures, Yu discloses the apparatus substantially as claimed by applicant. With regard to claims 2 and 20, Yu discloses a microfistula tube 20 that forms a passage between the anterior chamber and Schlemm's canal (see column 7, lines 25-30). The apparatus comprises a drainage canal 15 with a sharpened forward outflow portion 12 and a rear facing inflow portion 14 (see at least FIG 1, column 5, line 50 to column 6, line 67). The apparatus is sized and shaped to be introduced into Schlemm's canal at "an angle" which may comprise any angle, and is introduced at least partially within Schlemm's canal, regardless of rotational orientation, since the tube is round (see FIG 1). The apparatus may further comprise barbs or anchors to limit movement of the implant (see column 6, lines 10-15). With regard to applicant's recitation that the implant is "generally orthogonal to Schlemm's canal," the Examiner regards such a statement to be directed to the intended use of the claimed device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In

the instant case, applicant fails to disclose any structural limitation that allows for the orthogonal placement. Since both the prior art apparatus and the instantly claimed apparatus comprise cylindrical bodies with inflow ends, outflow ends, and anchor members, it is the position of the Examiner that the apparatus disclosed by Yu is capable of being placed in the orthogonal location claimed by applicant.

Yu fails to disclose that the apparatus comprises a plurality of longitudinally spaced openings in the outflow portion. However, Lynch discloses an ocular implant that is designed to extend and shunt fluid between the anterior chamber and Schlemm's canal of the eye. The implant comprises a plurality of spaced fenestrations or openings along the longitudinal axis of the implant in order direct shunted fluid to the collecting channels of the eye (see at least FIG 2 and column 8, lines 18-34). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add the openings disclosed by Lynch to the implant disclosed by Yu in order to direct shunted fluid to various collecting channels of the eye, as taught by Lynch.

With regard to claims 13-15, Yu discloses that the implant may comprise a sloped, conical end, thereby providing a distal end with a transverse dimension that varies along the axis (see at least FIG 1, column 5, lines 50-67).

With regard to claim 16, Yu discloses that the implant may comprise rearward pointing barbs that will prevent movement of the implant. Such barbs, if they are to prevent axial movement of the implant by pressing against surrounding tissue, comprise a surface that is transverse to the longitudinal axis of the implant (see at least column 6, lines 10-29).

With regard to claim 17, Yu illustrates that the implant is formed in one integral piece (see at least FIG 1).

With regard to claim 18, Yu illustrates that the implant comprises an unlabeled intermediate portion between the inflow portion 14 and outflow portion 12 (see at least FIG 1).

With regard to claim 19, it is well-known in the art of ocular implants that an implant that extends between the anterior chamber and Schlemm's canal of the eye most likely traverses the trabecular meshwork. For example, Lynch discloses that the implant traverses the trabecular meshwork, indicating that it is configured to reside within the trabecular meshwork (see column 11, lines 51-65). It is the position of the Examiner that applicant's claim language relates to a function of the claimed invention. . It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to function does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, applicant fails to disclose any structural limitation that allows for the placement within the trabecular meshwork of the eye. Since both the prior art apparatus and the instantly claimed apparatus comprise cylindrical bodies with inflow ends, outflow ends, and anchor members, and it is well-known in the art that shunts between the anterior chamber and Schlemm's canal pass through the trabecular meshwork, it is the position of the Examiner that the apparatus disclosed by Yu is capable of being placed within the trabecular meshwork claimed by applicant.

Response to Arguments

7. Applicant's amendment and arguments filed 20 December 2007 have been entered and considered, but are moot in view of the new grounds of rejection presented above.

8. Applicant's amendment to claim 2 with regard to the orthogonal implantation is considered by the Examiner to be supported by the illustration in Applicant's FIG 3.

9. Applicant argues that the implant disclosed by the prior art does not comprise "longitudinally spaced openings" in the outflow portion. However, Lynch teaches a series of openings spaced along the longitudinal axis of the disclosed implant in order to provide fluid communication with drainage pathways of the eye. Accordingly, it is the position of the Examiner that taken together with Yu, the references reasonably suggest an implant with an inflow and outflow portion with an axis therebetween with fenestrations or openings spaced along the axis of the implant in order to provide fluid communication with drainage pathways of the eye. Therefore, the instantly claimed invention is unpatentable over the prior art of record.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Patent Examiner
Art Unit 3761
25 February 2008

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761